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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,104	04/24/2001	Fritz Magerl	LUD-PT002-PA1083US	6204

3624 7590 11/19/2003

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UNITED PLAZA, SUITE 1600
30 SOUTH 17TH STREET
PHILADELPHIA, PA 19103

EXAMINER

CHEVALIER, ALICIA ANN

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

ab12

Office Action Summary

Application No.

09/701,104

Applicant(s)

MAGERL ET AL.

Examiner

Alicia Chevalier

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1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

Election/Restrictions

1. Newly submitted claims 16-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1, 3-13 and 15, drawn to composite/component.

Group II, claim(s) 16-18, drawn to process for forming a biocompatible medical component.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

2. The drawings were received on August 28, 2003. These drawings are acceptable.

WITHDRAWN REJECTIONS

3. The objections to the drawings and specification of record in paper #9, page 2, paragraphs #1 and #2 have been withdrawn due to Applicant's amendments in paper #11.

4. The 35 U.S.C. §112 rejections of record in paper #9, pages 2-5, paragraph #4 have been withdrawn due to Applicant's amendments in paper #11.

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5. The 35 U.S.C. §102 rejection of claims 1-15 as anticipated by Chu et al. (EP 0551574 A1) of record in paper #9, pages 5-7, paragraph #6 have been withdrawn due to Applicant's amendments in paper #11.

6. The 35 U.S.C. §103 rejection of claims 1-15 over Loher et al. (WO 96/19336) in view of Ellis (GB 2203342 A) of record in paper #9, pages 7-9, paragraph #8 have been withdrawn due to Applicant's amendments in paper #11.

NEW REJECTIONS

7. **The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 3-13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case claims 1 and 9 add the limitation "wherein individual fibers are distributed within the composite so that a majority of the fibers do not contact each other." The specification does not disclose that the fibers are excluded from contacting each

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other, nor any specific disclosure reciting the preferred orientation of the fibers. The specification on page 8, line 30+ recites "the key factor in such a component is the special progression and arrangement of continuous fibers." The specification further discloses on page 9, line 15+, "during fabrication in a thermoforming process, in particular via push-pull extrusion, the progression and alignment of the fibers can still be additionally controlled, and hence influenced." The specification alludes to the importance of the fiber alignment but never really discloses the preferred embodiment of the alignment. Furthermore, there is no explicit support for the negative limitations "so that a majority of the fibers do not contact each other."

Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. MPEP § 2173.05(i)

Upon removal of the new matter from the claims the 35 U.S.C. §102 and §103 rejections of record in paper #9 will be reapplied.

ANSWERS TO APPLICANT'S ARGUMENTS

10. Applicant's arguments filed in paper #11 regarding the 35 U.S.C. §102 and §103 rejections of record have been carefully considered but are moot due the new grounds or rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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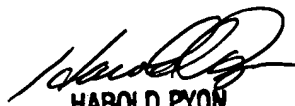
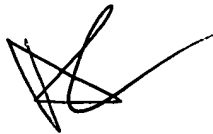
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Chevalier whose telephone number is (703) 305-1139. The Examiner can normally be reached on Monday through Thursday from 8:00 a.m. to 5:00 p.m. The Examiner can also be reached on alternate Fridays

If attempts to reach the Examiner are unsuccessful, the Examiner's supervisor, Harold Pyon can be reached by dialing (703) 308-4251. The fax phone number for the organization official non-final papers is (703) 872-9306. The fax number for after final papers is (703) 872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose phone number is (703) 308-0661.

ac
11/10/03



HAROLD PYON
SUPERVISORY PATENT EXAMINER
1/12

11/14/03